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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/082,521 | 02/23/2002 | Naoki Agata | 1000.06.003 | 8046 |
| 31076 | 7590 | 02/12/2004 | EXAMINER | |
| ILEX ONCOLOGY, INC. ATTN: FRANCES WINKLER 4545 HORIZON HILL BLVD. SAN ANTONIO, TX 78229 | | | JONES, DWAYNE C | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1614 | |

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/082,521

Applicant(s)

AGATA ET AL.

Examiner

Dwayne C Jones

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10NOV2003.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-7 and 9-20 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1,2,4-7 and 9-20 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1, 2, 4-7, and 9-20 are pending.
2. Claims 1, 2, 4-7, and 9-20 are rejected.

Response to Arguments

3. Applicant's arguments with respect to claims 1, 2, 4-7, and 9-20 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim has improper claim dependency because it depends onto itself, claim 4. This anomaly renders the claim vague and indefinite.
6. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim has improper dependency on cancelled claim 8. Consequently, this claim is ambiguous.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. Claims 1, 2, 4-7, and 9-17 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Agata et al. Agata et al. teach of administration of NM-3 along with dexamethasone and in combination with chemotherapeutic agents, such as doxorubicin, for the treatment of multiple myelomas and myeloma cells by increasing apoptosis and thus cell death, (see abstract).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1, 2, 4-7, and 9-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Agata et al. Agata et al. teach of administration of NM-3 along with dexamethasone and in combination with chemotherapeutic agents, such as doxorubicin, for the treatment of multiple myelomas and myeloma cells by increasing apoptosis and thus cell death, (see abstract). Although Agata et al. do not teach specifically teach of other chemotherapeutic agents besides doxorubicin, it would have been obvious to one having ordinary skill in the art to simply include other chemotherapeutic agents to treat multiple myelomas and decrease the proliferation of myeloma cells because these compositions are shown to increase apoptosis, (see abstract). Clearly, one having ordinary skill in the art would have been motivated to utilize other chemotherapeutic agents especially in view of the fact that Agata et al. disclose of the generic teaching of utilizing chemotherapeutic agents along with compounds of NM-3.

12. Claims 1, 2, 4-7, and 9-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Agata et al. in view of DiPiro et al. Agata et al. teach of administration of NM-3 along with dexamethasone and in combination with chemotherapeutic agents, such as doxorubicin, for the treatment of multiple myelomas and myeloma cells by increasing apoptosis and thus cell death, (see abstract). Although Agata et al. do not teach specifically teach of other chemotherapeutic agents besides doxorubicin, it would have been obvious to one having ordinary skill in the art to

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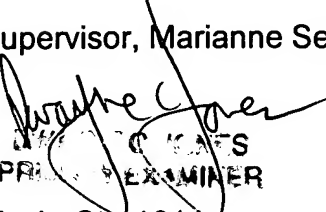
simply include other chemotherapeutic agents to treat multiple myelomas and decrease the proliferation of myeloma cells because these compositions are shown to increase apoptosis, (see abstract). The prior art reference of DiPiro et al. teaches of the chemotherapeutic coadministration of various chemotherapeutics, namely cyclophosphamide, vincristine and prednisone, (see page 1354). DiPiro et al. also teach of the administration of inter alia, doxorubicin, cisplatin and BCNU, (see pages 1354 and 1355). Moreover, it would have been obvious to the skilled artisan to select other types of chemotherapeutic reagents, especially in view of the DiPiro et al. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . . [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Accordingly, it would have been obvious to the one having ordinary skill in the art to combine these prior art teachings in order to arrive at the instantly claimed composition of isocoumarin derivatives, NM-3, with other chemotherapeutic agents, especially since all of these compounds are shown by the prior art to treat cancer and Agata et al. do in fact teach of the generic teaching of utilizing chemotherapeutic agents along with compounds of NM-3.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (571) 272-0578. The examiner can normally be reached on Mondays, Tuesdays, Thursday, and Fridays from 8:30 am to 6:00 pm.

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The official fax No. for correspondence is (703) 872-9306.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, may be reached at (571) 272-0584.


PRINCIPAL EXAMINER

Tech. Ctr. 1614
February 10, 2004